

Remarks

Claims 1-11, 16-18, 21-25, 27-31, 55-57, 61-63, and 66-71 are pending and under consideration in this application.

Claim Rejections Under 35 U.S.C. § 102(b)

Claim 71 stands rejected under 35 U.S.C. § 102(b) as being anticipated by Nieuwkerk *et al.* (U.S. Patent No. 5,438,128) (Nieuwkerk). (Office Action, page 2.) Applicants respectfully disagree but have amended the claim to facilitate prosecution.

An anticipation rejection under 35 USC § 102 requires a showing that each limitation of a claim is found in a single reference, practice, or device. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). The Examiner asserts Nieuwkerk teaches a method for convenient and rapid isolation of nucleic acids, plasmid purification by contacting the filter with cell lysate, a device for the isolation of nucleic acids comprising stacked membranes with a pore size of 0.1 to 12 microns and membranes secured by an insert. (Office Action, page 3.)

Applicants have amended independent claim 71 to recite “that said first filter layer retains cellular debris and biological macromolecules are isolated” to more clearly define the subject matter of the claims. Support for the amendment can be found, *inter alia*, in paragraphs [0037], [0040] and [0048] of the specification. The amendment does not add new matter. The method disclosed by Nieuwkerk uses multiple stacked membranes but there is no disclosure that the first membrane in the stack retains the flow of cellular debris. To the contrary, Nieuwkerk discloses that “plasmid DNA can be isolated from a crude bacterial lysate in a stepwise manner by first removing biomolecules and cellular contaminant material that do not bind to the ion exchange membranes.” (Nieuwkerk, column 7, lines 8-12.) Further, in the examples, Nieuwkerk discloses that cellular debris are removed by precipitation with potassium acetate yielding a “clear supernatant free of cellular particulate.” (Nieuwkerk, column 8, lines 36-48.) Thus, Nieuwkerk does not disclose a method where a “first filter layer retains cellular debris” and therefore does not anticipate the pending claims.

In view of the above Applicants respectfully request reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b).

Claim Rejections Under 35 U.S.C. § 103

Claims 1-11, 16-18, 21-25, 27-31, 55-57, 61-63 and 66-70 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Jones (WO 95/02049) in view of Nieuwkerk. (Office Action, page 5.) Applicants respectfully disagree but have amended claims to facilitate prosecution.

The Examiner asserts that the membranes of Jones inherently retard the flow of cellular debris and thus Jones in view of Nieuwkerk renders obvious the claimed invention (Office Action, page 9).

Applicants have amended independent claims 1, 31, 55 and 67 to recite, in part, that “said first filter layer retains cellular debris and biological macromolecules are isolated.” Support for the amendments can be found, *inter alia*, at paragraphs [0037], [0040], and [0048] of the specification. The amendments do not add new matter. Applicants note that Jones passes the target molecule (e.g.: DNA) through the first filter, but NOT through the second filter. That is, Jones binds the target molecule to the second matrix (instead of passing it through like the instantly claimed invention) and it is further noted that the methods taught by Jones necessarily include an elution step. For example see page 3, fourth full paragraph of Jones. The present claims are directed, in part, to methods where biological macromolecules are isolated without an elution step. As discussed above, Nieuwkerk does not disclose a method where a “first filter layer retains cellular debris” so therefore does not remedy the deficiencies of Jones. Therefore, all of the elements of the present claims are not taught or suggested by the cited art.

In view of the above, Applicants respectfully request reconsideration and withdrawal of the rejections under 35 U.S.C. 103(a).

Conclusion

All of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider

and withdraw all presently outstanding rejections. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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